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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/836,455	05/09/1997	MALAYA CHATTERJEE	304142000322	6310

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

Office Action Summary	Application No. 08/836,455	Applicant(s) CHATTERJEE ET AL.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on May 17, 2004.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-6, 11, 14-40, 42, 43, 46-59, 62, 63, 65 and 67-98 is/are pending in the application.
4a) Of the above claim(s) 1-5, 20-37, 39, 40, 42, 43, 46-56, 67 and 68 is/are withdrawn from consideration.

5) ☒ Claim(s) 6, 11, 16-19, 38, 59, 62, 63, 65, 70-76, 79, 81 and 89-98 is/are allowed.

6) ☒ Claim(s) 14, 15, 57, 58, 69, 77, 78, 80, and 82-88 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

1. The amendment filed May 17, 2004 is acknowledged and has been entered. Claims 41, 44, 45, 66, and 99 have been canceled. Claims 19, 69, 76-79, and 89 have been amended.

2. Claims 1-6, 11, 14-40, 42, 43, 46-59, 62, 63, 65, 67-98 are pending in the application. Claims 1-5, 20-37, 39, 40, 42, 43, 46-56, 67, and 68 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 14.

3. Claims 6, 11, 14-19, 38, 57-59, 62, 63, 65, and 69-98 are currently under prosecution.

Grounds of Objection and Rejection Withdrawn

4. Unless specifically reiterated below, Applicant's amendment filed May 17, 2004 has obviated the grounds of objection or rejection set forth in the Office action mailed December 17, 2003.

Response to Amendment

5. The amendment filed October 24, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is: "all of which are incorporated by reference", wherein the "all" includes reference to copending US Application No. 08/766,350, filed December 13, 1996. An incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. See 35 U.S.C. § 132(a). When a benefit claim is submitted after the filing of an application, the reference to the

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prior application cannot include an incorporation-by-reference statement of the prior application. Therefore, the incorporation-by-reference statement in the amendment to the specification introduces new matter and renders the amendment improper. See *Dart Industries v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980). See 1268 OG 89 (18 March 2003).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 14, 15, 57, 58, 77, 78, and 82-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

Claims 14, 15, 57, 58, and 82-88 are directed to a polynucleotide comprising only a portion of the sequence set forth as SEQ ID NO: 1 or SEQ ID NO: 3.

SEQ ID NO: 1 and SEQ ID NO: 3 encode the light and heavy chain variable regions of monoclonal antibody 11D10.

Because the claims are directed to a polynucleotide comprising only a portion of the sequences encoding either the light or heavy chain variable regions of the antibody, the claims encompass a genus of polynucleotides that vary markedly in both structure and function. However, the description of the genus of polynucleotides encompassed by the claims is limited to polynucleotides encoding the light and heavy chain variable regions of monoclonal antibody 11D10. Therefore, the written description of the presently claimed invention would not be sufficient to reasonably convey to the skilled

artisan that Applicant had possession of at least a substantial number of members of the genus because, absent an adequate description of at least a substantial number of the members of the genus of polynucleotides, the skilled artisan could not immediately envision, recognize, or distinguish at least a substantial number of those members. Accordingly, the claims encompass subject matter that is not adequately described to meet the written description requirement set forth under 35 USC § 112, first paragraph.

MPEP § 2163.02 states, “[a]n objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed’”. The courts have decided:

The purpose of the “written description” requirement is broader than to merely explain how to “make and use”; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the “written description” inquiry, *whatever is now claimed*.

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, “Written Description” Requirement (66 FR 1099-1111, January 5, 2001) state, “[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was ‘ready for patenting’ such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention” (*Id.* at 1104). The *Guidelines* further state, “[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus” (*Id.* at 1106); accordingly, it follows that an

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adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 57, 58, 69, 78, and 80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 57, 58, 69, and 80 are indefinite in the use of the designation 11D10 as the sole means of identifying the antibody to which the claims refer. The use of laboratory designations only to identify a particular antibody renders the claims indefinite because different laboratories may use the same laboratory designations to define completely distinct antibodies. Amendment of the claims to include the depository accession number of the monoclonal antibody or hybridoma producing the antibody is required, because deposit accession numbers are unique identifiers, which unambiguously define a given monoclonal antibody. For example, amending claims 57, 58, and 69 to recite, "wherein antibody 11D10 is produced by the hybridoma deposited under ATCC Accession No. HB-12020" can obviate this ground of rejection.

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Claim 78 presently depends from claims 7-10 and 12; and claims 7-10 and 12 have been canceled. Accordingly, the metes and bounds of the claimed subject matter cannot be ascertained.

Conclusion

10. The subject matter of claims 6, 11, 16-19, 38, 59, 62, 63, 65, 70-76, 79, 81, and 89-98 is free of the prior art and allowable. Claims 14, 15, 57, 58, 69, 77, 78, 80, and 82-88 are not allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
August 3, 2004

Jeffrey Siew
SUPERVISORY PATENT
EXAMINER
TC 1600
8/9/04